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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,028	12/02/2003	Glenn Butler	LS-002	4694
31647	7590	07/13/2007	EXAMINER	
DUGAN & DUGAN, P.C. 55 SOUTH BROADWAY TARRYTOWN, NY 10591			FARAH, AHMED M	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/726,028

Applicant(s)

BUTLER, GLENN

Examiner

Ahmed M. Farah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 29 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 21 is again rejected under 35 U.S.C. 102(b) as being anticipated by Hakky, US Patent No. 6,152,919.

Hakky discloses a laser resectoscopic apparatus and methods of use, the apparatus comprising:

a multi-lumen catheter/cannula 16 adapted to be disposed in a treatment site, the catheter including:

a fiber optic light distribution member 22 adapted to irradiate the treatment site with laser light (see Fig. 1 and col. 3, lines 1-10);

at least one irrigation lumen, which receives irrigation saline fluid from a fluid source 64 (see col. 3, lines 41-46); and

at least one aspiration lumen, which removes the irrigation fluid, along with blood, resected tissue and other debris from the treatment site (see col. 3, lines 46-50).

2. Claims 1, 3, 5-8, 10, 11, 13-22, 24-27 and 29 are again rejected under 35 U.S.C. 102(b) as being anticipated by Leckrone et al. US Patent no. 5,026,367.

Leckrone et al. disclose a laser angioplasty catheter system and methods of use, the catheter system comprising:

a plurality of optical fibers 41 adapted to irradiate the treatment site with laser light (see Figs. 1 and 5 and col. 4, lines 36-41);

at least one irrigation lumen 35, which delivers irrigation fluid, such as saline to the treatment site(see Figs. 5 and 10, and col. 4, lines 26-35);

at least one aspiration lumen 48, which removes the irrigation fluid, along with blood, resected tissue and other debris from the treatment site (col. 4, lines 52-60); and

a control means configured to control the flow rate of the irrigation/aspiration fluid as presently claimed (see col. 2, lines 61-68).

3. Claims 1, 10, 11, 13-22, 24-27 and 29 are again rejected under 35 U.S.C. 102(b) as being anticipated by Fox et al. US Patent No. 5,041,108.

Fox et al. disclose a catheter apparatus for treating a body lumen, the catheter comprising:

an optical fiber bundle 16 adapted to irradiate the treatment site with a laser light;

at least two irrigation channels 42, 44, adapted to deliver irrigation fluid, such as saline to the treatment site;

at least one suction channel 40 adapted to remove the irrigation fluid and other debris from the treatment site; and

a control means configured to control the laser source and the irrigation/aspiration sources as presently claimed (see Figure 1).

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4. Claims 1, 9, 12, 21 and 28 are again rejected under 35 U.S.C. 102(b) as being anticipated by Reynard US Patent No. 5,651,783.

Reynard discloses a phacoemulsification laser apparatus for treating glaucoma, the apparatus comprising:

- a multi-lumen catheter including:
- a fiber optic bundle adapted to irradiate the treatment site with a laser light;
- an irrigation lumen configured to deliver irrigation fluid to a treatment site;
- an aspiration lumen configured to remove debris from the treatment site; and
- a control means configured to control the functions of the laser source and the irrigation/aspiration lumens (see col. 11, lines 1-5 and claim 1).

As to claims 9 and 28, the light source is selected from the group comprising UV, visible, and IR light sources (see col. 2, lines 47-61).

As to claim 12, the aspiration line and at least one or more of the other catheter lumens are concentrically arranged (see Figs. 8 and 9).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 4 and 23 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. in view of Hareyama et al. US Patent No. 6,605,082.

Fox et al, describes above, do not teach the use of a temperature sensor to measure the temperature of the treatment site, or the arrangement of the optical fibers as recited in claims 4 and 23.

Hareyama et al. disclose an alternative treatment apparatus comprising a temperature sensor configured to measure the temperature of the tissue being treated. As to claims 4 and 23, the Examiner notes that the use of angled fiber/air interface is known in the art.

Therefore, at the time of the applicant's invention, it would have been obvious to one skilled in the art to modify Fox et al. in view of Hareyama and incorporate a temperature sensor to the device of Fox et al. to monitor the temperature of the treatment site in order to prevent unintended heating and/or burning of the tissues at or near the treatment site.

### ***Response to Arguments***

6. Applicant's arguments filed on March 28, 2007 have been fully considered but they are not persuasive. See the following:

A. With respect to the rejection of claims 21, 24-27, and 29 under 35 U.S.C. 102(b) as being anticipated by *Hakky*, US. Patent No. 6,152,919 (hereinafter *Hakky*), the applicant argues that *Hakky* is directed to "a resectoscope for laser coagulation and

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cutting of prostatic or bladder tissue,” and therefore fails to teach treatment of “a wound site” or “a fiber optic light distribution system to irradiate the wound site with light” as recited in the instant claims.

As to the method claims 24-27 and 29, applicant’s arguments are persuasive. Hence, the Examiner withdraws the rejection of the method claims under *Hakky*.

However, as to the apparatus claim 21, the Examiner maintains the rejection because the recitation in the claim that the optic fiber system is “adapted to irradiate the wound site with light” is directed to an intended use of the device. The recited term fails to incorporate any structural and/or functional limitation to the claim and, therefore, is not given a patentable weight. Moreover, the optic fiber system of *Hakky* is capable to irradiate light energy to a wound site as claimed.

B. With respect to the rejection of claims 1, 3, 5-8, 10, 11, 13-22, 24-27 and 29 under 35 U.S.C. 102(b) as being anticipated by Leckrone et al., US. Patent No. 5,026,367 (hereinafter *Leckrone*), the applicant states that *Leckrone* is directed to a laser catheter system comprising optical fibers adapted to remove “obstructions within blood vessels such as **plaque** in coronary, femoral, and other arteries.” Similarly, the applicant argues that contrary to his invention, *Leckrone* fails to teach an optical fiber system adapted to irradiate a wound site with light.

In response to this argument, the examiner maintains rejections of the apparatus claims 1, 3, 5-8, 10, 11, and 13-22 due to the reasoning discussed above. With respect to the method claims 24-27 and 29, as recognized by the applicant, *Leckrone* teaches

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methods for removing **plaque** within a blood vessel. The Merriam-Webster's online dictionary defines the word "**plaque**" as an "atherosclerotic lesion," and the word "**lesion**" is defined as: injury, harm, or an abnormal change in structure of an organ or part due to injury or disease. Hence, the Examiner's position is that since *Leckrone* teaches a method for removing/treating plaque within a blood vessel, which is defined as an abnormal change in structure of the organ due to injury or disease, he inherently teaches a method for treating a wound site as broadly as claimed.

C. With respect to the rejection of claims 10, 11, 13-22, 24-27 and 29 under 35 U.S.C. 102(b) as being anticipated by Fox et al., US. Patent No. 5,041,108 (hereinafter *Fox*), the applicant makes arguments that are similar to the arguments described above. In addition, the applicant argues that since the rejection does not address independent claim 1, the reference cannot anticipate claims 10, 11, and 13-17.

In response to the arguments directed to the intended use of the device 1, 9 and 12, see the examiner's response/position as detailed above. In response to second argument, the omission of claim 1 from the list of the rejected claims was an inadvertent typographical error.

D. With respect to the rejection of claims 1, 9, 12, 21, and 28 under 35 U.S.C. 102(b) as being anticipated by Reynard US Patent No. 5,651,783, the applicant makes similar arguments as described above.



In response to the arguments directed to the intended use of the device, see the examiner's response/position as detailed above. As to the method claims 21 and 28, the Examiner withdraws from the rejection.

***Allowable Subject Matter***

Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-

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4765. The examiner can normally be reached on Mon, Tue, Thur and Fri between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marmor II Charles can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ahmed M Farah  
Primary Examiner  
Art Unit 3735



July 8, 2007.